IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327** **JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Diane Kropf, et al. v. Ethicon, Inc., et al.***	**Case No. 2:12-cv-01202**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO LIMIT THE CASE-SPECIFIC OPINIONS AND TESTIMONY OF RICARDO GONZALEZ, M.D.

Plaintiffs, Diane Kropf and Joseph Kropf, by and through their undersigned counsel, hereby respectfully submit the following Memorandum in Support of Plaintiffs' Opposition to Defendants' Motion to Limit the Case-Specific Opinions and Testimony of Ricardo Gonzalez, M.D.

EXECUTIVE SUMMARY

Defendants' Motion to Limit the Case-Specific Opinions and Testimony of Ricardo Gonzalez, M.D. should be denied. Ricardo R. Gonzalez, M.D. ("Dr. Gonzalez") is well-qualified to offer his reliable opinions based on his expert review, analysis of the medical records, and independent medical exam in this case. Dr. Gonzalez's opinions were reached as the result of performing a proper differential diagnosis, an accepted and reliable methodology and analysis. He reviewed Mrs. Kropf's medical records and the deposition testimony in this case, considered her medical history as well as his knowledge, training, and experience as a

urologist and female pelvic floor surgeon, conducted a medical examination of Ms. Kropf on November 16, 2015, and concluded that her injuries were caused by Defendants' defective pelvic mesh products. Defendants' objections to Dr. Gonzalez's opinions go to the weight of his opinions and should be an issue for the factfinder at trial.

For these reasons, and as further set forth below, Dr. Gonzalez should be permitted to testify consistent with his expert report, and Defendants' motion to limit Dr. Gonzalez's opinions on *Daubert* grounds should be denied.

I. FACTS AND OPINIONS RELATED TO THIS MOTION

Plaintiffs initiated this action by Complaint in the United States District Court for the Western District of Missouri on April 3, 2012. *See* Doc. No. 1. Plaintiffs designated Ricardo R. Gonzalez, M.D. as their case-specific causation expert regarding Plaintiff's injuries caused by the implantation of the Defendants' devices. *See* Plaintiffs' Designation and Disclosure of Case-Specific Expert Witnesses, **attached hereto as Exhibit "A."**

The opinions of Dr. Gonzalez, a urologist and female pelvic floor surgeon, are the subject of this motion. Dr. Gonzalez is one of a small group of American physicians who are board certified in the obstetrics and gynecology subspecialty of Female Pelvic Medicine and Reconstructive Surgery. *See Curriculum Vitae* of Ricardo R. Gonzalez, M.D., at pp. 1, **attached hereto as Exhibit "B."**

In forming his opinions in this case, Dr. Gonzalez reviewed Mrs. Kropf's medical records, including the records surrounding her mesh implant surgery and removal surgery, the deposition testimony of Mrs. Kropf, Dr. Patricia Murray, and Dr. Charles Beamon, the Plaintiff Fact Sheet, relevant medical literature, and internal documents from the Defendants. Additionally, he conducted an examination of Mrs. Kropf. Dr. Gonzalez then performed a

complete differential diagnosis considering all potential causes of Mrs. Kropf's injuries. *See* Case-Specific Expert Report of Ricardo R. Gonzalez, M.D., **attached hereto as Exhibit "C."** His findings and opinions on the cause of Mrs. Kropf's injuries are set forth in his expert report. *Id.*

II. ARGUMENT

A. The Daubert Standard of Admissibility

The introduction of expert opinion testimony is governed by Federal Rule of Evidence 702. Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified ... by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed.R.Evid. 702.

The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm–O–Disk, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

B. Dr. Gonzalez's Opinions are Relevant and Admissible.

1. All risks of the Prolift and TVT-O are relevant and admissible.

Defendants seek to preclude Dr. Gonzalez from testifying about all of the possible complications and risks that have not yet been experienced by Mrs. Kropf. Defendants claim that Dr. Gonzalez should be forbidden from discussing these complications and risks but ignore the

purpose and relevance of introducing such evidence. Namely, evidence of mesh-associated complications and risks not yet suffered by Mrs. Kropf are highly probative of Plaintiffs' design defect claim – i.e. whether the mesh devices were defectively designed, as well as Defendants' notice and knowledge of risks and complications associated with these mesh devices, which speaks to Plaintiffs' design defect and failure to warn claims, Plaintiffs' future damages, and punitive damages.

Any and all complications and risks caused by the Prolift and TVT-O are relevant to prove Plaintiffs' design defect claim. The totality of the complications caused by a product and the underlying mechanisms that cause those complications are relevant to whether a product is safe, and to evaluate whether possible safer alternative treatment options exist. In addition, complications and risks about the product which are known to Defendants are relevant to Plaintiffs' design defect claims, as well as the issue of punitive damages. This evidence speaks to the reasonableness and recklessness of Defendants' conduct in the face of complications and risks it knew caused substantial harm to women implanted with their devices. Thus, all of the complications and risks attendant to the Prolift and TVT-O, including those not experienced by Mrs. Kropf, are relevant to the instant action and admissible under the Federal Rules of Evidence.

Defendants cite to the federal MDL Court rulings in *Bellew* v. *Ethicon, Inc.*, No. 2:13-cv- 22473 (S.D.W.Va. 2014), and *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4536876, at *4 (S.D. W. Va. Aug. 30, 2016)*), in support of their argument. However, the same court ruled differently on this issue in *Cisson v. C.R. Bard (In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation)*, 2013 WL 3282926 (S.D.W.Va. 2013), a pelvic mesh cases involving Bard's Avaulta device. In *Cisson*, the court denied the defendants'

motion *in limine* seeking to preclude evidence or argument regarding complications that were not experienced by the plaintiff. There, the Court found:

> From the parties' arguments, it appears that there are two steps in the complications suffered by Avaulta patients. First, the collagen component of the Avaulta Plus product is alleged to increase the inflammatory response of the body. This inflammatory response may then lead to a host of other complications, including erosion, persistent delayed healing, dehiscence and abscess, among others. Evidence of a heightened inflammatory response appears relevant as to all bellwether plaintiffs; it is the more specific complications that the inflammatory response may lead to which are at issue here. Evidence as to Bard's knowledge of these more specific complications may very well be relevant to certain issues in this case. Accordingly, Bard's motion *in limine* on this issue is DENIED.

Cisson, 2013 WL 3282926 at *6.

Lastly, Dr. Gonzalez should be permitted to explain mesh-related complications that Mrs. Kropf has not yet experienced to educate the jury on her damages in this case. If Defendants disagree with the likelihood of her suffering such future injuries, they may cross-examine Dr. Gonzalez on these points. However, this testimony is relevant and necessary to the jury's consideration of the harm Mrs. Kropf has suffered and is likely to suffer in the future. Accordingly, Defendants' Motion to exclude all evidence of complications other than those experienced by Plaintiffs should be denied.

2. Dr. Gonzalez's discussion of internal documents for the purpose of explaining his opinions is permissible.

Defendants assert that Dr. Gonzalez should not be allowed to testify as to what they "knew." But Defendants' knowledge provides important context for certain opinions. For example, to prove their negligence claims, Plaintiffs will have to show that Defendants knew or should have known of the basis for the warning.

When Dr. Gonzalez discusses what Defendants "knew," he is simply providing context for his opinion that Defendants should have given stronger warnings. In the Bard litigation, the Court held that experts could discuss internal documents "for the purpose of explaining the basis for his or her opinions." *In re C.R. Bard*, 2013 WL 3282926, at *12. Dr. Gonzalez does not intend to do any more than that when testifying about Defendants' knowledge at trial.

C. Dr. Gonzalez Does Not Offer Any Impermissible Legal Conclusions

Defendants seek to preclude Dr. Gonzalez from offering an opinion as to whether the Prolift or TVT-O contained a design defect. However, Dr. Gonzalez is well-qualified to opine on the potential complications these defects cause and their effects on Mrs. Kropf. His opinions are based on his extensive knowledge, training, and experience as a board-certified urologist and female pelvic floor surgeon.

This Court has ruled several times that familiarity with peer-reviewed, published literature, and experience in treating mesh complications provides a sufficient basis upon which to offer an opinion regarding the in vivo behavior of mesh. *Edwards v. Ethicon, Inc*., C.A. No. 2:12-cv-09972 (Dkt. No. 129, pp. 19-20) (citing prior opinion from *In re* Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2:12-MD-02327, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (holding that a urogynecologist qualified to offer opinions regarding polypropylene characteristics and in vivo behavior based on having explanted multiple polypropylene mesh products, and reviewed applicable literature); *Winebarger v. Boston Scientific Corp*., 2015 WL 1887222, *5 (S.D.W.Va.2015) (citing prior decisions in concluding that defendant's contention that plaintiff's urogynecologist expert was not a "biomaterials expert" did not prevent design defect testimony which was based upon extensive clinical experience and review of literature).

Dr. Gonzalez has extensive knowledge and experience in both the implantation and surgical removal of pelvic mesh products and treatment of mesh-related complications. *See* Case-Specific Expert Report of Ricardo R. Gonzalez, M.D., **attached hereto as Exhibit "C."**

Accordingly, Defendants' argument is not a basis to exclude Dr. Gonzalez's opinions, but rather to properly subject him to cross-examination. Therefore, Defendant's Motion to Limit the Case-Specific Opinions and Testimony of Ricardo Gonzalez, M.D. should be denied.

D. Dr. Gonzalez's Opinions Regarding the TVT-O are Relevant

In Section "C", Defendants merely rehash the same groundless argument asserted elsewhere in their Amended Memorandum, that Dr. Gonzalez cannot provide any opinions regarding any injuries from the TVT-O that Plaintiff has not yet experienced. Plaintiffs addressed this same argument in Section "B" above, and the same response applies here, as well. In the interests of brevity, Plaintiffs incorporate by reference their Response in Section "B" above and the citation of authority and reasoning therein, as if restated here in its entirety. Again, any and all complications and risks caused by the TVT-O are relevant to prove Plaintiffs' design defect and failure to warn claims.

E. Dr. Gonzalez's Opinions Regarding Curling, Roping, Contracture, Shrinkage, and Degradation are Permissible.

Defendants argue that Dr. Gonzalez offers general and specific causation opinions that the mesh in the Prolift and TVT-O devices causes complications due to its propensity to curl, rope, contract, shrink, and degrade. Plaintiffs have not proffered Dr. Gonzalez as a general causation expert. Therefore, Defendants' argument is moot. However, to the extent Dr. Gonzalez presented generalized opinions pertaining to Mrs. Kropf's injuries in his expert report, those opinions were based on his training, education, and experience. Dr. Gonzalez reviewed Mrs. Kropf's medical records, conducted an examination of Mrs. Kropf, and holds his opinions to a

reasonable degree of medical certainty. *See* Case-Specific Expert Report of Ricardo R. Gonzalez, M.D., **attached hereto as Exhibit "C."** To the extent Defendants disagree with Dr. Gonzalez's expert report, they may cross-examine Dr. Gonzalez at trial.

F. Dr. Gonzalez Will Not Testify as to the Adequacy of the Warnings of the Prolift or TVT-O Devices

Plaintiffs do not oppose the relief requested in Section "E" of Defendants' Memorandum and agree to exclude certain testimony and opinions of Dr. Gonzalez as it pertains to the adequacy of the warnings for Plaintiffs' Prolift and TVT-O devices. Plaintiffs will not put forth the testimony or opinions of Dr. Gonzalez as it pertains to warnings of the Prolift or TVT-O devices as this will be addressed by the designated general causation expert if necessary.

III. CONCLUSION

WHEREFORE, Plaintiffs respectfully request that the Court deny Defendants' Motion to Limit the Case-Specific Opinions and Testimony of Ricardo Gonzalez, M.D.

Respectfully submitted,

KLINE & SPECTER, PC

Dated: May 24, 2019 BY: _____

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